

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

IN RE: VALSARTAN N-  
NITROSODIMETHYLAMINE (NDMA),  
LOSARTAN, and IRBESARTAN PRODUCTS  
LIABILITY LITIGATION

Civil No. 19-2875 (RBK/JS)

ORDER

The Court having held numerous discovery conferences with the parties regarding plaintiffs' discovery directed to the API and Finished Dose Manufacturing defendants (hereinafter collectively referred to as "defendants"); and the Court most recently holding a conference call on December 18, 2019; and the parties and the Court having finalized plaintiffs' document requests directed to defendants, as well as the custodians and search terms to be used for defendants' document and ESI production; and this Order intending to memorialize the Court's rulings; and for all the reasons stated by the Court on the record,

IT IS HEREBY ORDERED this 23<sup>rd</sup> day of December, 2019 as follows:

1. Attached as Exhibit A are plaintiffs' Court approved Requests for Production of Documents directed to defendants. These Requests shall be responded to without objection.

2. Attached as Exhibit B is the list of the Court approved Custodians for ZHP, Huahai US, Princeton, Solco, Syncores, and Prinbury.
3. Attached as Exhibit C is the list of the Court approved Mylan Custodians.
4. Attached as Exhibit D is the list of the Court approved Teva Custodians.
5. Attached as Exhibit E is the list of the Court approved Hetero Custodians.
6. Attached as Exhibit F is the list of the Court approved Aurolife and Aurobindo USA Custodians.
7. Attached as Exhibit G is the list of the Court approved Torrent Custodians.
8. Attached as Exhibit H is the list of the Court approved search terms to be used by defendants; and it is further

ORDERED plaintiffs' discovery shall be answered by the deadlines in the Order entered on December 13, 2019, Doc. No. 318; and it is further

ORDERED defendants' documents shall be produced on a rolling basis. The first group of responsive documents and ESI shall be produced no later than March 2, 2020, with subsequent rolling productions no later than the first day of each month; and it is further

ORDERED plaintiffs and defendants shall meet and confer regarding custodians and categories of documents to prioritize.

s/ Joel Schneider  
JOEL SCHNEIDER  
United States Magistrate Judge

# Exhibit A

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

**IN RE: VALSARTAN  
PRODUCTS LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Judge

Honorable Joel Schneider,  
Magistrate Judge

**PLAINTIFFS' THIRD AMENDED SET OF REQUESTS FOR PRODUCTION OF  
DOCUMENTS TO ALL API AND FINISHED-DOSE MANUFACTURING  
DEFENDANTS**

**TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:**

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, and in accordance with the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, and in the Order filed on December 13, 2019, as well as the Court's Order on macro discovery issues filed on November 25, 2019, Plaintiffs propound the following third amended discovery requests upon each API and finished dose-manufacturing defendant:<sup>1</sup>

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<sup>1</sup> Each request is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303); the parties' representations as reflected in the record of the December 11, 2019 discovery hearing; and the Court's oral rulings at the December 11, 2019 discovery hearing.

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## DEFINITIONS:

**“Active Pharmaceutical Ingredient” (“API”)** is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.” 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

**“API Manufacturer”** is defined as any entity that manufactures the active pharmaceutical ingredient (API) for valsartan.

**“Finished Dose Manufacturer”** includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term “finished dose manufacturer” also includes entities who hold ANDAs.

**“Communication(s)”** means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

**“Documents”** includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term “Document” includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. “Documents” also includes the content of any applicable computer database.

**Relevant Time Period:** Unless otherwise specified, the relevant time period applicable to all requests is the time period specified by the Court.

**“Regulatory and Regulatory Authority”** refers to United States and foreign regulatory agencies.

**“TPP”** refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payers, and any other health benefit provider in the United States of America and its territories.

**“Valsartan”** means any drug with valsartan as an active ingredient, including the API for valsartan on its own, as well as all finished drug formulations of valsartan.

**“You,” “your” or “defendant”** shall be used interchangeably and refers to the parties to which these requests are directed.

## **DOCUMENTS TO BE PRODUCED**

### **I. CORPORATE ORGANIZATION**

1. Produce organizational charts setting forth the corporate organization for each named defendant, from January 2010 to the present as follows:
  - a. General corporate organizational charts for each defendant, including any affiliated entities involved in the manufacture, testing, distribution, or sale of valsartan;
  - b. Medical affairs/clinical affairs department, or the equivalent;
  - c. Quality assurance department, or the equivalent;
  - d. Manufacturing department, including any departments involved in the manufacturing process for valsartan;
  - e. Procurement Department;
  - f. Sales department;
  - g. Marketing department;
  - h. Research and development department;
  - i. Department(s) responsible for designing, funding, or supervising clinical trials (including all Phase I, II, III, and IV);
  - j. Regulatory department;
  - k. Department responsible for epidemiology and/or statistical analysis;
  - l. Department responsible for providing professional education to physicians;
  - m. Department(s) responsible for establishing or maintaining relationships involving valsartan, with any other defendant named in this MDL.
2. Produce organizational charts or similar documents setting forth:
  - a. All corporate officers;
  - b. All members of the Board of Directors;
3. To the extent you conduct business relating to the manufacture, distribution, or marketing of valsartan with any other defendant in the above-captioned MDL, produce documents, including contracts, invoices, payment records, and communications, demonstrating the nature, extent, and length of this business relationship.

### **II. RELEVANT CUSTODIANS**

4. Produce documents identifying the corporate employees or retained third parties responsible for or involved in the (1) manufacture, (2) testing, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments, (6) regulatory activities, (7) communications with regulatory agencies, (8) distribution, (9) production, (10) packaging, (11) sale, (12) marketing, and (13) communications with private individuals or entities regarding safety, bioequivalence, purity, contamination, and pricing, with regard to valsartan.

### **III. POLICIES AND PROCEDURES**

5. Produce all final versions of policies, procedures, standard operating procedures, or protocols for or relevant to the (1) manufacture, (2) testing, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments, (6) regulatory activities, (7) communications with regulatory agencies, (8) production, (9) distribution, (10) packaging, (11) sale, (12) marketing, and (13) communications with private individuals or entities, regarding safety, bioequivalence, purity,



contamination, and pricing, with regard to valsartan, and/or the ingredients thereof. In addition, provide all indexes or lists of the requested documents.

#### **IV. AGREEMENTS**

6. Produce all agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) the manufacturing process, (2) testing for bioequivalence, purity, or contamination, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments of bioequivalence, purity, or contamination, (6) regulatory activities, (7) communications with regulatory agencies, (8) production, (9) distribution, (10) packaging, (11) sale, (12) marketing, (13) communications with private individuals or entities, regarding safety, bioequivalence, purity, contamination, and pricing, and (14) procurement of components or ingredients, with regard to valsartan and/or its ingredients.
7. Produce all agreements, memoranda, and payment or expense records, with regard to any attempt by defendant to retain, engage or otherwise provide financial support or item of value to any person with regard to proposed or actual scientific or medical study of valsartan.
8. Produce all agreements to engage any third party to represent your interests before the FDA or any regulatory authority, with regard to valsartan.
9. Produce all agreements with regard to the retention of persons in any medical or scientific discipline to study, assess or analyze the safety, purity, or contamination of valsartan for or on behalf of any defendant.

#### **V. INTRA-DEFENDANT COMMUNICATIONS**

10. All communications between or among any of the defendants with regard to. (1) the manufacturing process, (2) testing capable of indicating purity, bioequivalence, or contamination, (3) quality assurance related to purity, bioequivalence, or contamination, (4) risk assessment with regard to contamination or the use of solvents, (5) medical and clinical assessments of risks related to impurity or contamination, (6) communications with regulatory agencies regarding bioequivalence, purity, or contamination, (7) terms or conditions of distribution, (8) sale numbers, (9) pricing, and (10) procurement or use of solvents, with regard to valsartan.

#### **VI. ANDA AND DMF**

11. To the extent any ANDA file for valsartan sold in the United States was not produced in whole or in part during Core Discovery, produce the entire file.
12. Produce all correspondence with the FDA concerning any ANDA for valsartan sold in the United States, whether or not ultimately approved, including prior to the relevant time period set by the Court.
13. Produce all documents containing the list of ingredients in valsartan sold in the United States, which were provided to any regulatory authority, beginning from the date you first began development of the process for manufacturing the API for valsartan sold in the United States [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].
14. Produce all documents relating to New Drug Applications filed by you with regard to valsartan sold in the United States, beginning from the date you first began development of the process

for manufacturing the API for valsartan sold in the United States [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].

15. Produce all complete drug master files for valsartan sold in the United States, to the extent not produced to date. [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].

#### **VII. LITIGATION AND DOCUMENT PRESERVATION**

16. Produce all document retention or destruction policies.
17. [WITHDRAWN]
18. [WITHDRAWN]

#### **VIII. MANUFACTURING**

19. Produce all documents with regard to the manufacturing process for the active pharmaceutical ingredient in valsartan, including any modifications thereto, as described and set forth on the record during the December 11, 2019 Court hearing.
20. Produce all documents with regard to the machines, materials, and substances (including but not limited to new or recycled solvents, tainted or contaminated solvents) utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan, including specifications, manuals, material safety data sheets, machine settings and calibrations, and any modifications thereto, as described and set forth on the record during the December 11, 2019 Court hearing.
21. Produce all documents (including photographs or video) with regard to any testing or inspections of valsartan for purity or contamination consistent with the scope of relevant testing as set forth in ¶ 8 of the Court's ruling on macro discovery issues (Dkt. 303). As stated in the Court's November 25, 2019 Order, this includes tests showing unknown and unidentified testing peaks or general toxic impurities in valsartan API or valsartan, any test that could identify the presence of nitrosamine contamination, and testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the valsartan API and valsartan. As ordered during the December 11 Court hearing, the relevant time period for ZHP's production of the testing listed in Plaintiffs' December 10, 2019 letter shall date back to the start of the implementation of the manufacturing process in 2007 for ZHP, and to the date on which the manufacturing process was first implemented for other API manufacturers.
22. Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of valsartan sold by you or any of your affiliated entities, including any quality assurance and testing, and any modifications thereto, as described and set forth on the record during the December 11, 2019 Court hearing.
23. Produce the patent(s) for any patented manufacturing process for the valsartan API or the finished dose versions of your VCDs.
24. Deleted by Court Order.
25. Produce documentation demonstrating the name, address, and role of any third party which supplied you with valsartan or any ingredient, material, or component used in the manufacture of valsartan, and any evaluation or testing thereof. For finished dose manufacturers this request is limited to the supply to you of valsartan API.

26. Produce all certificates of analysis or similar documents concerning analysis of the purity or contents of valsartan, including the catalysts and solvents used in the tetrazole ring process, and documents and communications concerning the same.
27. Produce documentation identifying (1) each lot, batch, or other production quantity of valsartan manufactured, purchased, or sold by defendant (including discarded or recalled lots or batches), (2) the dates of manufacture for each, (3) the solvent(s) (including residual or reused solvents) utilized in the manufacture of each, and (4) any information you obtained with regard to potential risks of the use of any solvent utilized, including residual or reused solvents.
28. Produce documentation of all scientific journal articles submitted to any academic or scientific publication, written or drafted in whole, or in part, by your employees or scientists or third parties who received funding or other forms of compensation from you, regarding the manufacturing of valsartan, including the final version, any drafts, edits, and peer reviewed feedback.
29. All communications and documents exchanged between you and any third party, regarding the manufacturing process associated with the creation of valsartan, including but not limited to the use of solvents, the tetrazole ring formation process, testing, and contamination issues.

**IX. BIOEQUIVALENCE**

30. All documentation of the bioequivalence of any valsartan sold or manufactured (in whole or in part) by you to the Reference Listed Drug ("RLD"), including but not limited to, testing, communications with the FDA, communications with customers, suppliers, or other third parties, and certifications of bioequivalence.
31. All marketing materials referencing the bioequivalence of valsartan manufactured, distributed, or marketed by you.
32. All documents and communications regarding the identification by any person or entity of any valsartan manufactured, utilized, or sold by or to you as not being bioequivalent to the RLD.
33. All documents and communications relevant to valsartan entries in the FDA's "Orange Book."
34. Deleted by Court Order.

**X. TESTING**

35. Produce all documents setting forth or addressing the results of any testing (including chromatography) of valsartan that had the potential to directly or indirectly identify impurities or contamination.
36. Produce all documentation with regard to the first test that indicated impurity or contamination of valsartan that was potentially due to a nitrosamine, whether or not identified as nitrosamine contamination at the time.
37. Produce all documentation with regard to each notification to defendant of impurity or contamination of valsartan that was, or potentially was, due to a nitrosamine, whether or not identified as nitrosamine contamination at the time. In connection with this request, separately identify the first such notification.
38. [WITHDRAWN]
39. Produce all documents with regard to evaluation by an employee of defendant or a third party, with regard to the health risks of valsartan contamination as limited by the Court's Order.

40. Produce documentation of all studies of the ingredients, impurities, and actual or potential contamination, of valsartan conducted by any third parties, including, but not limited to, those conducted by Contract Research Organizations (CRO), educational institutions, publicly or independently funded groups, competitors, trade groups or associations, regulatory entities, irrespective of whether such studies were conducted at the direction of Defendant.
41. Produce documentation of any report or analysis made known to Defendant with regard to the relationship between the use of contaminated valsartan and potential or confirmed injuries; and the review of same by any employee or consultant of Defendant.
42. Provide documentation of the results of any clinical or animal study regarding valsartan conducted with potentially contaminated valsartan during the relevant time period, whether or not sponsored by, financed by, undertaken by, or suggested by Defendant, and any internal analysis thereof,
43. Produce documentation of any epidemiology studies or analyses known to defendant regarding valsartan, including but not limited to, any provided to or received from any regulatory authority, together with the underlying data including for example SAS data sets, and any internal analysis thereof.
44. Produce complete documentation of (a) all testing relevant to determination of purity, bioequivalence, or contamination, prior to any recall, of valsartan you manufactured or sourced, (b) all testing relevant to determination of purity, bioequivalence, or contamination,, after any recall, of valsartan you manufactured or sourced, (c) the results of the foregoing testing; (d) any such testing that was considered but not performed before or after any recall, including the reason(s) why such testing was not performed, and (e) to the extent any lot, batch, or other production quantity was not tested for impurities, bioequivalence or contamination, complete documentation with regard to the reason(s) why no such testing was performed. The scope of testing responsive to this request, other than bioequivalence testing, is defined by Paragraph 8 of the Court's ruling on macro discovery issues (Dkt. 303).

#### **XI. NITROSAMINES AND CONTAMINATION**

45. Produce complete documentation identifying each lot, batch, or other production quantity of valsartan, (a) confirmed to be contaminated and the quantification of the contamination; (b) assumed to have been contaminated and the quantification of the contamination; (c) confirmed not to be contaminated; (d) assumed not to be contaminated, and (e) confirmed or assumed to be contaminated.
46. Produce complete documentation of any testing for any nitrosamine compound, including but not limited to NDMA, NDEA, NMBA, and any other nitrosamine or carcinogenic contaminant in valsartan, or any other API or finished drug manufactured, formulated, distributed, or sold by the answering defendant, as limited by the Court's Order.
47. Produce complete documentation of any testing or research conducted by you or a third party on your behalf to determine the existence or quantification of contamination in any valsartan API or finished drug formulation.
48. Produce complete documentation with regard to the analysis of health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance, conducted by you or any third party on your behalf.
49. Produce all studies, data, or other scientific or medical information reviewed or considered by any employee or third party on your behalf with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.

50. Produce all formal or informal reports or complaints by or to Defendant or any other person or entity to your knowledge, with regard to valsartan contamination.
51. Produce all documents known to you, embodying any analysis or opinion by any person or entity, regarding the potential health risks of nitrosamine contamination of valsartan.

## **XII. REGULATORY CORRESPONDENCE AND DOCUMENTS**

52. Produce all regulatory documentation and communications with regard to contamination or recalls of valsartan, as limited by the Court's Order.
53. Produce all regulatory documentation and communications with regard to the use of solvents, tetrazole ring formation, and potential impurities or contamination in connection with the manufacturing process for valsartan, as limited by the Court's Order on macro discovery issues (Dkt. 303).
54. Produce transcripts, notes, memoranda, or other documentation of any hearings or other proceedings or meetings which took place at or with any regulatory agency relating to the actual and/or potential contamination or recall of valsartan, as limited by the Court's Order on macro discovery issues (Dkt. 303).
55. Produce all documents with regard to any FDA Advisory Panel meetings regarding valsartan contamination.
56. Produce all Establishment Inspection Reports (including foreign regulatory equivalents of Establishment Inspection Reports) and related documentation (including photographs or video) concerning your facilities or the facilities of any other defendant used in the manufacture, fabrication, packaging, distribution, or sale of valsartan, as limited by the Court's Order on macro discovery issues (Dkt. 303).
57. Produce all documents relating, referring to or embodying all inspection reports (including 483s, detention reports, and warning letters, or consent decrees, including foreign regulatory equivalents) which pertain in any way to valsartan contamination or any facility in which contaminated valsartan was manufactured, as limited by the Court's Order on macro discovery issues (Dkt. 303).
58. Produce complete documentation regarding any CAPAs (Corrective and Preventative Actions) relating to the manufacture of valsartan, including documentation showing what caused the CAPA to be opened and/or closed, as limited by the Court's Order on macro discovery issues (Dkt. 303).
59. Produce all documentation, and related communications, of any complaints or third party communications to or from any regulatory agency with regard to actual or potential valsartan contamination, as limited by the Court's Order on macro discovery issues (Dkt. 303).
60. Produce all documentation, including source files, for any MAUDE or other adverse event reports submitted to any regulatory agency with regard to cancer, or any injury potentially caused by valsartan contamination, and any related communications, as limited by the Court's Order on macro discovery issues (Dkt. 303).
61. Produce complete files for all formal or informal adverse event reports and/or MedWatch reports concerning cancer, or any injury potentially caused by valsartan contamination, including: a) causation analyses, b) summaries (including, but not limited to, computerized data), analysis or interpretations of any such adverse event report(s) (including any post-marketing submissions); and c) documents which discuss or refer to any adverse event report, or any summary, analysis or interpretation thereof, as limited by the Court's Order on macro discovery issues (Dkt. 303).



62. Produce all databases maintained by you concerning both domestic and international formal and informal adverse event reports and/or MedWatch reports, including the underlying medical information and raw data maintained by you, with regard to reports of cancer, or any injury potentially caused by contaminated valsartan, as limited by the Court's Order on macro discovery issues (Dkt. 303).
63. Produce all filings with the Securities and Exchange Commission (SEC), addressing the sale of contaminated valsartan, including Forms 10-K, 10-Q, 8-K, and proxy statement (Schedule 14A), whether such filings are tentative, final, definitive, or supplemental.
64. Produce complete documentation of any communications with any state regulatory or health authorities regarding valsartan purity, bioequivalence, contamination, or pricing, as limited by the Court's Order on macro discovery issues (Dkt. 303).
65. Produce complete documentation of Defendant's efforts to comply with Current Good Manufacturing Practices (cGMPs), and any actions or inactions that did not meet or might not have met cGMPs, with regard to the valsartan manufacturing process and use or reuse of solvents in the valsartan manufacturing process, including, but not limited to, documents identifying any cGMP consultants retained by Defendant, documents regarding cGMP compliance provided to the FDA, and responses to FDA 483s and Warning Letters regarding cGMP compliance, as limited by the Court's Order on macro discovery issues (Dkt. 303).

### **XIII. COMPLAINTS AND RECALLS**

66. Produce complete documentation with regard to each implementation of a recall due to contamination of valsartan.
67. Deleted by Court Order.
68. Produce all final recall notices with regard to contamination of valsartan.
69. Produce all documents setting forth or addressing any communications with any customer or consumer relating to the recall (or non-recall) of valsartan due to contamination.
70. Produce all communications directly with physicians relating to the recall (or non-recall) of valsartan due to contamination.
71. Produce all communications with any person or entity to which, or from which, you purchased or sold valsartan, with regard to valsartan contamination.
72. Produce all documents and communications with regard to the scope of any recall considered or implemented with regard to valsartan contamination.
73. Produce all documents and communications with regard to any complaint or concern raised by any person or entity relating to the purity, bioequivalence, or contamination of valsartan.
74. Produce all documents or communications concerning any actual or potential import or export alerts relating to valsartan contamination.
75. Produce all documents and communications concerning any buybacks or refunds that you paid to any purchasers of valsartan in the United States related to valsartan contamination.
76. Produce all communications (and drafts) to or from Defendant regarding recall of valsartan related to valsartan contamination, including lists sufficient to show all persons or entities who received communications.
77. Produce documents sufficient to identify any person or entity retained by Defendant with regard to the recall of valsartan due to nitrosamine contamination.
78. **Note: this request is only directed to API manufacturer defendants and FDA liaison defendants.** Produce all documents setting forth or with regard to, communications with Novartis concerning valsartan impurity, bioequivalence, or contamination.

#### **XIV. WARRANTIES AND STATEMENTS**

79. Produce all versions of defendant's labeling, package inserts, patient leaflets, and medication guides for valsartan in the United States, together with a chart of the approval dates and in use dates for all versions that were utilized in the sale and marketing of valsartan.
80. Produce all statements regarding purity, bioequivalence, and contamination provided to medical professionals, purchasers including TPPs, consumers, wholesale distributors, retail pharmacies, and other direct and indirect purchasers of valsartan, for each NDC, Batch Number, and Lot Number of valsartan sold in the United States during the relevant time period.
81. All advertisements, and sales and marketing materials for valsartan, and charts setting forth the approval date and in use dates, for each.
82. [WITHDRAWN]
83. Produce all communications between you and any medical professional or medical association concerning the risk of cancer, or any injury potentially associated with valsartan contamination.
84. [WITHDRAWN]
85. Deleted by Court Order.
86. Produce all communications with healthcare providers regarding the purity, bioequivalence, or, recall status, of valsartan.
87. Produce all public statements (and drafts) issued by Defendant regarding valsartan purity, bioequivalence, or contamination of valsartan.
88. [WITHDRAWN]
89. [WITHDRAWN]
90. Produce all communications with the Centers for Disease Control (CDC), National Institutes of Health, World Health Organization, U.S. Drug Enforcement Agency, U.S. Department of Justice, U.S. Attorney General, any regulatory agency, or any state agency, relating to valsartan contamination.
91. Produce all documents relating to any investigative subpoenas and subsequent investigation from the United States Department of Justice, United States Congress, and/or any other federal or state entity, relating to valsartan contamination.
92. Produce all documents relating to, referring to or embodying any discussion or submission between defendant and any state government regulatory agency or any state medical society concerning reimbursement for valsartan purchases.

#### **XV. SALE AND DISTRIBUTION**

93. Produce complete documentation setting forth and/or demonstrating the complete supply and distribution chain for valsartan purchased, sold, or distributed by you, from the manufacture of the API through the final sale to the consumer.
94. Produce all documents relating to the sale and distribution of valsartan that reflect NDC, batch number, and lot number.
95. Produce documents sufficient to show all sales of valsartan to wholesalers, distributors, retailers, and consumers, including the total net sales, total number of pills and/or units sold, unit price, unit cost, profit margin, and market share by state or territory.
96. Produce all documentation relating to the due diligence performed in selecting an API or finished dose manufacturer from which you purchased valsartan, including but not limited to policies and standard operating procedures.

97. Produce all communications received from any API manufacturer or finished dose manufacturer with regard to the manufacturing process, purity, bioequivalence or contamination relating to valsartan.
98. Produce complete documentation of the basis for Defendant's decision to purchase valsartan from any API or finished dose manufacturer, including documents you reviewed or relied on to make those decisions.

**XVI. IDENTIFICATION OF PURCHASERS**

99. Produce documents sufficient to identify all persons and entities (including consumers and TPP entities) who purchased, reimbursed, or paid or otherwise compensated you for valsartan you manufactured, sold or distributed in the United States. If available, produce documents sufficient to show these individuals' or entities' names, last known mailing addresses and email addresses, last known telephone numbers, date(s) of purchase, NDC Code(s), Batch Number(s), and Lot Numbers.
100. Produce all communications between or among you and any named plaintiff acting as a class representative, including the named consumer representatives and/or named TPP representatives, with regard to the sale of valsartan.

**XVII. SALES AND PRICING**

101. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
102. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
103. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
104. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
105. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
106. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
107. Produce documents sufficient to show (i) the customers to whom you sold valsartan API or valsartan finished dose, (ii) unique identifiers for product sold (e.g., lot number, batch number, NDC code, etc.), (iii) quantities of valsartan API or valsartan finished dose sold, (iv) dates of sale, and (v) net and gross price per sale. The parties will meet and confer about the scope and form of data based on the particular data maintained by each Defendant and thereafter to determine the extent to which additional information will be needed including information required for class certification.
108. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
109. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.
110. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.



111. Withdrawn by Court-approved agreement reached on the record during the December 11, 2019 hearing.

#### **XVIII. AVAILABLE DATA SOURCES**

112. Produce all documents relating to all IMS, Verispan, MediSpan, Scott-Levin, PriceCheck, ImpactRx, First DataBank, or other pharmaceutical industry data products purchased and or subscribed to or available to you regarding valsartan.
113. Produce all data or reports generated by IMS, CMS, or Verispan, or any comparable third party person or entity (including, but not limited to, Medi-Span, ImpactRx, and First DataBank), in whatever format it was received, relating to the sale, prescription, marketing, promotion, or detailing of valsartan from date of launch to the present for valsartan, including:
- a. IMS National Prescription Audit data, including TRx, NRx, extended units, retail sales dollars and retail sales price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.
  - b. IMS National Sales Perspective data, including total units, extended units, total sales dollars, and price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.
  - c. CMS national Health Expenditures and Drug Utilization data, including TRx, NRx, Medicaid percentage paid, extended units, retail sales dollars, and retail sales price, with regard to valsartan.
  - d. Verispan Vector One National (VONA) data, including TRx, NRx, extended units, retail sales dollars, and retail sales price, with regard to valsartan. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.
114. Produce all documents relating to any coupon or co-pay assistance you made available to consumers for valsartan.

#### **XIX. DEFENDANT-SPECIFIC REQUESTS**

##### **A. To Mylan:**

115. Deleted by Court Order.
116. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan's Nashik facility, including but not limited to the September 2016 inspection and resulting warning letter and November 2018 inspection and warning letter.
117. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan's Morgantown, WV facility, including but not limited to documents regarding inspections which occurred in November of 2016, March 2018, April 2018, resulting correspondence with the FDA regarding these inspections (including but not limited to, notes, presentations and documents created as a result of in person meetings with regulatory officials).
118. Deleted by Court Order.
119. Produce all documents and communications regarding your contract with Lantech Pharmaceuticals for the recovery and further use of any and all solvents used in valsartan manufacturing.

**B. To Aurobindo:**

120. All documents and communications regarding your contract with Lantech Pharmaceuticals for the recovery and further use of any and all solvents used in valsartan manufacturing.

**C. To Teva:**

121. Produce all full and complete documents and document families previously produced in core discovery, including all documents previously withheld by Teva from the custodial file of Constance Truemper.
122. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Teva's finished dose manufacturing facilities, including but not limited to the Jerusalem Oral Solid Dose facility, and documents regarding a 2010 inspection which resulted in a warning letter from the FDA.

Dated: August 30, 2019

/s/ Adam Slater

Adam M. Slater

**Mazie Slater Katz & Freeman, LLC**

103 Eisenhower Parkway

Roseland, NJ 07068

Tel.: (973) 228-9898

aslater@mazieslater.com

Daniel Nigh

**Levin Papantonio**

316 South Baylen Street

Pensacola, FL 32502

Tel.: (850) 435-7013

dnigh@levinlaw.com

Ruben Honik

**Golomb & Honik, PC**

1835 Market Street

Suite 2900

Philadelphia, PA 19103

(215) 278-4449

[rhonik@golombhonik.com](mailto:rhonik@golombhonik.com)

Conlee Whitely

**Kanner & Whitely, LLC**

701 Camp Street

New Orleans, LA 70130

(504) 524-5777

[c.whiteley@kanner-law.com](mailto:c.whiteley@kanner-law.com)

**In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination  
Products Liability Litigation  
MDL No. 2875**

**Exhibit B**

**ZHP, Huahai US, Princeton, Solco, Syncores, and Prinbury Custodians**

<u>Name</u>
Min Li
Qiangming Li
Wenquan Zhu
Wenbin Chen
Jucal Ge
Baozhen (Jennifer) Chen
Wei Cheng
Yuelin Hu
Dongqin Wang
Peng Wang
Wei Chen
Wenling Zhang
Peng Dong
Liohng (Linda) Lin
Yanfeng (Lucy) Liu
Ting (Ada) Zhou
Ying (Miya) Xiong
Jie Wang
Minda Cai
Mi Xu
Sheng Zhong
Hongchao Li
Minli Zhang
Xiaoming Liu
Weiwei Xu
Min Xu
Min Hu
Gaozhe Zheng
Xiaodi Guo
Hai Wang
John Iozzia
Chris Keith
Remonda Gergis
Lijie Wang

**In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination  
Products Liability Litigation  
MDL No. 2875**

Name
David Ayres
Eric Tsai
Yun (Sophie) Tian
Tiyun (Tina) Liu
Taufaung (Alex) Liu
Eric Gu
An Jianguo
Huang Luning
Xianhua Zhang
Jin Yun
Xiaxia Kuang
Wei (Helena) Tong
Tian Zhang
Xiong Fe
Hongliang Wang
Yinhua Tang
Jian Ye
Wenping Hu
Chaohua Bao
Xiao Tan
Qiang Zhou
Tong Wu
Cunxiao (Jenson) Ye
Xiaohong Zhao
Meng Zheng
Y.F. Chen
Caifeng Zhao
Lijin Jiang
Xiaohui Zhou
Minfa Wang
Guangyu (Erin) Luo
Lesley Zhu
Guanping Hu
Youqing Zheng
Yuping Chen
Xiaoling Li
Nan Tong

**In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination  
Products Liability Litigation  
MDL No. 2875**

<u>Name</u>
Chunmin Xu
Jun Du
Jun Wang
Yong Chen
Hu Wang
Yanhua Meng
Zhizhang Ding
Fengfeng Yan
Zunjun Liang
Lingfang Wang

**Products Liability Litigation  
MDL No. 2875**

**Exhibit C - Mylan Custodians**

<b>Last Name</b>	<b>First Name</b>
Akula	Satish
Akula	Pulleswarara Rao
Alturi	Muralikrishna
Anabathula	Venkata
Basade	Imtiyaz
Bhadane	Sachinkumar
Bird	Cassandra
Carson	Jennifer
Gandy	Brian
Gomas	Antony
Indukuri	Jayababu
Jyothibas	Abbineni
Kasbekar	Uday
Khambete	Makarand
Kimble	Ambica
Kolla	Naveenkumar
Koski	Eddie
Krishna Reddy	G. Chinni
Kumar	K. Sarat
Kumar	N. Anjani
Kumar	K. Naveen
Kupec	Kim
Lakshmi	Marayana
Lynn	Steve
Mahanti	Satish
Malki	Reem
Mandada	Sharat Babu
Medikonduri	Suresh
Molnar	Lance
Murthy	GNVSN
Mutode	Valentine
Nampally	Chandu
Noe	Okey
Owens	Walter
Paten	Chetan
Patil	Durvas
Plastina	Michael
Rajagopal	I.
Rao	TRK Jagannadha
Rao	Srinivasa
Rawjee	Yasir
Reddy	G. Narender

**Products Liability Litigation  
MDL No. 2875**

**Exhibit C - Mylan Custodians**

<b>Last Name</b>	<b>First Name</b>
Sethi	Madhuresh
Smith	Jeffrey
Srivinas	Vasireddy
Subrahmanyam	MVRBS
Talton	Wayne
Tamalampudi	Satya Balaji
Vaidya	Pradeep
Vandzura	Valerie
Varna	SVSJ Rama
Workman	Dave

**In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination  
Products Liability Litigation  
MDL No. 2875**

**Exhibit D**

**Teva Custodians**

<u>Name</u>
Barreto, Dan
Binsol, Tony
Bonilla, David
Chandrasekar, Rajesh
Clark, Napoleon
De Notaristefani, Carlo
Delgaudio, Joyce Ann
Delicato, Tony
De Vito, Joseph
Falkin, Marc
Fluch, Joerg
Galownia, Kevin
Gatt, Elton
Gray, Elisabeth
Hess, Brian
Hatt, David
Karlsson, Stefan
Koleto, Christina
Korcia, Avi
Lyons, Claire
McBryan, Danny
Nassall, Jens
Nudelman, Raphael
Osmian, Michelle
Pastore, Jill
Pavlov, Kiril
Redmond, Michael
Sawyer, Corey
Segura, Jose Luis
Schwartz, Orit
Singh, Usha
Sualhi, Rana
Tomsky, Scott
Truemper, Constance



**In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination  
Products Liability Litigation  
MDL No. 2875**

Vadsola, Narendra
-------------------

Wang, Lijie
-------------

**In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination**

**Products Liability Litigation**

**MDL No. 2875**

**Exhibit E - Hetero USA Custodians**

<b>Last Name</b>	<b>First Name</b>
Akula	Seshu
Chelak	William
Chigurupati	Raghu
Indukuri	Somaraju
Kankula	Rajesh

**Products Liability Litigation  
MDL No. 2875**

**Exhibit F - Aurolife and Aurobindo USA Custodians**

<b>Last Name</b>	<b>First Name</b>
Ale	Srinivasulu
Bheeminemi	Sudhir
Burns	Daniel
Chada	Krishna Reddy
Doshi	Bhadresh
Gorijavolu	Prasad
Gupta	Jasleen
Jackowski	Jeffrey
John	Blessy
Kota	Venkata
Lucas	Steve
Martinez	Sandra
Palew	David
Patel	Arpit
Shirshikar	Milind

**Products Liability Litigation**

**MDL No. 2875**

**Exhibit G - Torrent Custodians**

<b>Last Name</b>	<b>First Name</b>
Agrawal	Vineet
Attinger	Bernadette
Chitty	Dawn
Gegenheimer	Kelly
Gorontla	Saroja
Jaiswal	Sushil
Panwar	Swati
Patel	Brijesh
Patel	Kalpesh
Perry	Sue
Prajyat	K
Reddy	Neravelta
Rivera	Jocelyn
Shah	Dhrumit
Shah	Dilkesh
Sheth	Paras
Shubham	J
Siddhaye	Anupama

# Exhibit H

(*11025* or *18253* or *202223* or *203311* or *203820* or *20473* or *205347* or *20939* or *23491* or *24544* or *24873* or *29392* or *77530* or *78030* or *90483* or *90642* or *90866* or *91235*)
EIR or "establishment inspection report"
OAI or "official action indicated"
"voluntary action indicated"
*diethylamine or "*diethyl amine"
*dimethylamine or "*dimethyl amine"
*dimethylformamide or DMF
*dimethylmethanamide
*ghost*
*NDEA*
*NDMA*
*nitra*
*nitrite*
*nitrosa*
*nitroso*
*NMBA* (deferred to after JPML decision)
*trosomine*
(Form483) or (Form /3 483) or (483 /3 letter) or (483 /3 warn*) or (704 pre/3 b)
C2H6N2O or "(CH3)2NN=O" or "CH32NN=O" or "(CH3)2NC(O)H" or CH32NCOH or C3H7NO or "(CH3CH2)2NH" or CH3CH22NH or C4H11N or "(CH3)2NH" or CH32NH or C2H7N or "(C2H5)2NNO" or C2H52NNO or C4H10N2O
carcin*
deviat* /5 cancer* or deviat* /5 toxic or or deviat* /5 hazard* or deviat* /5 fatal
FDA /10 warning
gene* /3 mutat*
genotoxic*
solvent /5 cancer* or solvent /5 toxic or or solvent /5 hazard* or solvent /5 fatal
solvent* /5 contamin*
(test* /5 canc*) AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))
tetrazol*
Valisure*

**<term> (no modifiers)^**

^Except if run against custodians in management over more than one facility, in which case to be run as indicated in agreed to procedure.

Last Name	First Name
Agrawal	Atul
Akhtar	Saleem
Amin	Pankaj
Arasu	
Arista	
Arroyo	
Baker	Peter
Barreto	
Barrowcliff	
Bellamy	
Bernard	Tonia
Bizjak	
Boyd	Justin
Bretz	Paula
Brown	Darren
Cartwright	
Casale	
Chapman	Johnathan
Charity	Antony
Chester	Bonita
Clausen	
Cosgrove	
Cruz	
Dezan	
Dickinson	Gwyn
Dobbin	
Dombrowski	
Donald	Steven
Dong	Eric
Eban	
Ernst	
Estrella	Maria
Etminan	
Ford	Susanna
Frazier	Laurie
Gavini	
George	Jogy

**Last Name Standalone  
UNLESS IF First Name  
Exists, THEN (Last Name  
/3 First Name) OR (Last  
Name AND <Regulatory  
Modifiers>)**

Ghoshal	Rabin
Gidado	
Goga	
Goga	Michael
Hall	Patrice
Hallas	
Harouaka	
Hebert or Della or Dellareese	
Hicks	Kellia
Higgins	Brooke
Huaren	
Hustedt	
Johansen	
Jones	Latoria
Karapetyan*	
Khan	Farhana
Khurana	Sangeeta
Kristensen	
Lopez Rubet	
Maldonado	
Mankind	
Mansournia	
Marcisin	
Martinez	Miguel
Mason	James
Mathew or Mathews	Lata
Mayasandra	Pal
Melende	
Min	Ko
Mistler	
Motamed	
Motta	
Mueller	
Narula	
Navas	
Nguyen	Truong
Oladimeji	
Panicker	
Patel	Nayan
Philopoulos	
Pitts	Simone
Podaralla	Satheesk
Pottgard	
Priester	
Pyramides	
Quartarolo	



Ray	Marcus
Razzaghi	Frederick
Roberts	Daniel
Roy	Melissa
Schwartz	Paul
Shah	Dipesh
Skanchy	
Srivasta	
Srivastava	Rajiv
Stieg	
Sweeney	
Szestypalow	
Tomasso	
Ulysse	
Upadhyay	Pratik
Verdel	
Wakijira	Chaltu
Wang	Zhao
Warnick	
Xu	Atul
Young	Rochelle
Yuscious	
Zaklady	
Zamil	
Zamperini	
Zhen Zhou	

("adverse event*" or AER) and (<drug name> or <solvents> or <facility names>)
"changes being effected"
"prior approval supplement"
adulterat*
alert*
CAPA or corrective pre/3 "preventive action"
CFR or eCFR or "code of federal regulations" or USC or "United States Code" or "Title 21"
Citizen* pre/3 Petition
(Establishment pre/3 Inspection)
import* /3 (ban or alert or restrict*)
inadequat*
inspect*
investigat*
major /3 change
(master /3 file) and (<drug name> or <solvents>)
minor /3 change
moderate /3 change
Monthly /3 update
(official pre/3 action* /4 indicat* )
observation*
OOS or "out of spec*" or "out-of-spec"
OOT or "out-of-trend" or "out of trend"
PADER* and (<drug name> or <solvents> or <facility names>)
VAI or (voluntary pre/3 action* /4 indicat*)
violat*
warn*

**<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <regulatory modifiers> OR <facility names>)**

{bottle pre/2 lies) or Eban
bury or burie* or conceal*
cGMP* or {current pre/5 manufacturing) or GMP*
"cover up*" or coverup* or "cover-up"
crash* or disaster*
data /4 integrity or data /4 reliabl*
delet* or destroy* or remov* or trash* or shred*
hide* or suppress*
whistleblow*

**<Term> AND (<Drug  
Name> OR (<Solvents>  
AND NOT <other drug  
names>) OR <regulatory  
modifiers> OR <inspect>  
OR <manufacturing  
modifiers> OR <medical  
modifiers> OR <facility  
names>)**

"anion-exchange" or anionexchange or "anion exchange"
"ion-exchange" or ionexchange or "ion exchange"
*PCRC*
aberran*
abnorm*
ALS
bioequiv*
CAPA or corrective pre/5 action
Chromato*
complain*
contami*
degradant* or impurit*
detect*
EI-MS or EL-MS or "electron ionization"
elude*
fail*
fatal*
GC or "GC-FID" or GCMS or "GC-MS"
hazard*
headspace
heat
HPLC-UV
HS
incomplet* /5 data*
LCMS
mass spectro*
method /5 qualification
noise*
noti* w/5 pharm*
obscure*
observation*
peak*
press /4 release
preventative /5 action
problem*
puri*
quality

**<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR <manufacturing modifiers>)**

recall*
repe* /4 error*
residu*
retrospec*
risk*
signal*
spectro*
spike*
suitab*
toxic*
unknown* or unk or unks
validat*

"PROCESS I" or "PROCESS II"
assay*
assessment*
batch /5 records
biocompat*
byproduct*
CAPA or corrective pre/3 "preventive action"
certificat*
change* /3 control*
change* /5 process*
COA or certificat* pre/3 analys*
concentra*
condensa*
conversion*
critical /4 change
crude*
deviat*
diastereo*
discrepanc*
error*
esterficat*
expir*
*formaldehyde*
malfunct*
material* /3 loss*
moiety or moieties
process /5 change
quench*
reagent*
reclaim*
recover*
recycl*
repack* or "re-pack*"
resal*
resell*
reuse*
ring*
solvent*
suppress*
TEA or Triethyl*
temperature

**<Term> AND (<Drug  
Name> OR (<Solvents>  
AND NOT <other drug  
names>))**

TIN or Tributyl*
yield*

bladder*
blood*
cancer* or precancer* or pre-cancer*
colon*
death* or dead or fatal
esophag*
gastro*
intestin*
kidn* or renal*
laten*
leukemia*
liver*
lymphoma*
muta*
myeloma*
NHL or non-hodgkin*
toxicolog*
onset*
oncolog*
ovar*
pancrea*
prostate*
stomach*

**<Term> AND (<Drug  
Name> OR (<Solvents>  
AND NOT <other drug  
names>))**



AWP or "average wholesale price" or WAC or "wholesale acquisition cost"
best /3 pric*
bulk /3 suppl*
impairment
IRR
manufactur* /3 cost*
marginal /5 cost*
market* /5 share*
net /5 profit*
net /5 valu*
NPA
NPV
rate /10 return
rebate*
sourc* w/5 agree* or sourc* w/5 anal* or sourc* w/5 contract* or sourc* w/5 forecast* or sourc* w/5 plan* or sourc* w/5 strat*
suppl* w/5 agree* or suppl* w/5 anal* or suppl* w/5 contract* or suppl* w/5 forecast* or suppl* w/5 plan* or suppl* w/5 strat*
SWOT or (strength pre/7 threat*)
writ* pre/5 off
(ABDC or Amerisource* or "American Health Packaging" or AHP) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(AG) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or gross or gross or loss)
(amerisource* ) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(ANDA) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(ASB) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)

**<Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))**

(Authorized /4 generic) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share)
(average or avg) AND (pric* or cost* or margin* or profit* or revenue*)
(avg ) AND (pric* or cost* or margin* or profit* or revenue*)
(boehringer ingelheim) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(cardinal) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(contract ) AND (distrib* or PBM)
(cost* ) AND (analy* or forecast* or plan* or strat*)
(CVS*) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(Epic) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(ESI) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(Express*) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(IMS) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or
(IQVIA) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or
(Kroger) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(mckesson) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(operat* w/5 margin*) AND (margin* or profit*)
(Optum*) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(pric*) AND (decreas* or increas* or list* or strat* or expect* or project*)
(recall) AND (loss or impair* or write* or reimburs* or indemn* or charg* or replace*)

(Redoak) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or loss)
(retail) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or
(Rite*) AND (pric*)
(sales ) /5 (expect* or project*)
(var* ) /5 (cost*)
(variable ) /5 (cost*)
(Walgreen* or WBDA) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)
(Walmart) AND (pric* or cost or market* or AWP or WAC or profit or margin* or stock or share or indemn* or indemn* or loss)

Alembic
ABDC or Amerisource* or "American Health Packaging" or AHP
Amerigen
ANDA
Auro* or APL or APUSA
boehringer ingelheim
Bristol
Camber
Cobalt
distribut*
Forest
Hetero
Huahai
Indoco
Ivax
Jubilant
Lantech*
Macleod*
Matrix
Mylan
Novartis
Par
Prinston
Qualanex
Ranbaxy
Sandoz
Syncore
Synthon
Teva
Torrent
Unichem
Watson
Zhejiang*
ZHP

**<Term> AND (<Drug  
Name> OR (<Solvents>  
AND NOT <other drug  
names>))**

*Valsartan*
amlodipine*
Diovan*
Exforg*
HCT or HCTZ
sartan or sartans

**<drug names modifiers>**

*azide*
*formaldehyde*
*-N3*
*xylene*
acid*
aqueous*
chloramin*
HNO2
hydrochlor*
N-3*
NaNO*
tolue*
Tributyl* or TIN
Triethyl* or TEA
zinc /3 chloride
ZnCl*

**<solvents modifiers>**

"Abbreviated New Drug Application" or ANDA
CDC or "Centers for Disease Control"
CDER or "Center for Drug Evaluation and Research"
DEA or "Drug Enforcement Administration" or "Drug Enforcement Agency"
"Environmental Protection Agency" or EPA or USEPA or "US-EPA" or "1200 Pennsylvania Avenue"
"Food and Drug Administration" or FDA or USFDA or "US-FDA" or "College Park"
NIH or "National Institutes of Health"

**<regulatory modifiers>**

Agency
inspect*
regulat*

<inspect modifiers>



backup /3 data
impurit* and degradant*
recall*
residu*
solvent*
spike*
test*
unknown /3 peak or unknown /3 spike or unknown /3 impurit* or unknown /3 contamin*

**<manufacturing modifiers>**

"adverse event*" or AER*
bladder*
blood*
cancer* or precancer* or pre-cancer*
colon*
death* or dead or fatal
esophag*
gastro*
intestin*
kidn* or renal*
laten*
leukemia*
liver*
lymphoma*
MedWatch* or "Safety Information and Adverse Event Reporting"
muta*
myeloma*
NHL or non-hodgkin*
toxicolog*
onset*
oncolog*
ovar*
PADER*
pancrea*
prostate*
stomach*

**<medical conditions  
modifiers>**

analys*
AWP
cost*
decreas*
distrib*
expect*
gross
impairm*
increas*
indem*
list*
loss*
margin*
market*
net
PBM
plan
pric*
profit*
project*
recall*
revenue*
share*
stock*
strat*
WAC
write*

**<economic modifiers>**

<b>TO BE DETERMINED</b>
Plaintiffs have just received the lists provided by Defendants and are still determining how to best search for facility names, as many facilities appear to be just referred to by the city name.

**<facility names modifiers>**

ABPI
AEMPS
Agency /3 Therapeutic
AIFA
ALIMS
ANMAT
BDA
BfArM
"British Pharmaceutical Industry"
"Bulgarian Drug Agency"
Canad* /3 Health
"Central drugs standard control"
CEP
DKMA
EMA
European /3 medic*
"European Medical"
Fimea
"Health Canada"
Health* /5 Agency
Hong Kong /7 "Drug Office"
HPRA
IMA
MEB
Medical /4 agency
"Medical Products Agency"
MFDS
MHRA
Ministry /3 Health
Ministry /5 drug
MPA
NAMMD
NHS
NIHS
NoMA
NPRA
OGYEI
PHARMAC
SAMLV
SAMR
SCMA
SIDC
"State Administration for Market"
SUKL
Swissmedic

**<foreign regulatory agency  
modifiers>**

TGA
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"Therapeutic Goods Administration"
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**SEARCH TERMS PROCEDURE****1. Search Terms**

The Primary Search Terms and Modifiers lists attached hereto as Exhibits A and B shall be used for searching of custodial records subject to the procedure set forth herein.

**2. Standalone Terms**

a) The following terms shall remain on the standalone terms list but can be tested and refined further if a need is shown after documents are collected and preliminarily reviewed:

- i. \*diethylamine or "\*\*diethyl amine"
- ii. \*dimethylamine or "\*\*dimethyl amine"
- iii. \*dimethylformamide or DMF
- iv. \*dimethylmethanamide
- v. \*ghost\*
- vi. \*NDEA \*
- vii. \*NDMA\*
- viii. \*nitra\*
- ix. \*nitrite\*
- x. \*nitrosa\*
- xi. \*nitroso\*
- xii. \*trosomine\*
- xiii. C<sub>2</sub>H<sub>6</sub>N<sub>2</sub>O or "(CH<sub>3</sub>)<sub>2</sub>NN=O" or "CH<sub>3</sub>2NN=O" or "(CH<sub>3</sub>)<sub>2</sub>NC(O)H" or CH<sub>3</sub>2NCOH or C<sub>3</sub>H<sub>7</sub>NO or "(CH<sub>3</sub>CH<sub>2</sub>)<sub>2</sub>NH" or CH<sub>3</sub>CH<sub>2</sub>2NH or C<sub>4</sub>H<sub>11</sub>N or "(CH<sub>3</sub>)<sub>2</sub>NH" or CH<sub>3</sub>2NH or C<sub>2</sub>H<sub>7</sub>N or "(C<sub>2</sub>H<sub>5</sub>)<sub>2</sub>NNO" or C<sub>2</sub>H<sub>5</sub>2NNO or C<sub>4</sub>H<sub>10</sub>N<sub>2</sub>O
- xiv. tetrazol\*
- xv. gene\* /3 mutat\*
- xvi. genotoxic\*
- xvii. carcin\* (but may modify if needed)
- xviii. deviat\* /5 cancer\* or deviat\* /5 toxic or deviat\* /5 hazard\* or deviat\* /5 fatal (but may modify if needed)
- xix. FDA /10 warning (but may modify if needed)
- xx. solvent /5 cancer\* or solvent /5 toxic or solvent /5 hazard\* or solvent /5 fatal (but may modify if needed)
- xxi. solvent\* /5 contamin\* (but may modify if needed)
- xxii. Valisure\* (but may modify if Valisure comes up for a reason other than its role in relation to detecting nitrosamines).

b) The following terms (1) when used against data of custodians working only at a particular facility would be run as standalone terms; and (2) when used against data of custodians in management over more than one facility would be run with <term> AND (<Drug Name> OR <Solvents> OR <Facility Name>), but can be tested and refined further to be <term> AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>)) if needed:

- i. EIR or “establishment inspection report”
- ii. OAI or “official action indicated”
- iii. “voluntary action indicated”
- iv. (Form483) or (Form /3 483) or (483 /3 letter) or (483 /3 warn\*) or (704 pre/3 b)

**3. Manufacturing, Medical Conditions, Economic Terms, Entities**

- a) The search string for these primary terms categories shall be: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>)) where <other drug names> will be an agreed to list of the names of each other non-valsartan (or other sartan depending on the JPML’s ruling) drug manufactured by the defendant running the modifiers;
- b) Plaintiffs will identify a subset of these terms that they believe need to be run with <Term> AND (<Drug Name> OR <Solvents>) instead (i.e. without excluding other drug names), which will be subject to testing and sampling as to the differential results;
- c) Any terms still in dispute after such testing, sampling, and meet and confers will be promptly brought to the Court for resolution.



**4. QA-Testing, cGMP, and Regulatory**

- a) The search string for these shall be: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>) OR [other categories of modifiers]);
- b) The Parties will negotiate any further modifications in either direction (e.g. narrowing or broadening), if needed, once documents have been collected and initially reviewed.
- c) Any terms still in dispute after such testing, sampling, and meet and confers will be promptly brought to the Court for resolution.

**5. 31 Terms Completely Objected to by Defendants**

- a) Defendants will run hit counts using the search string agreed upon for each particular term for those terms Defendants objected to (highlighted in yellow on search terms lists);
- b) The hit counts will be reviewed, documents sampled if necessary, and the Parties will meet and confer on how to narrow the terms if needed;
- c) If the Parties cannot agree, they will promptly bring the issue to the Court for resolution.